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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/067,148	05/26/93	MONTAGNIER L	3493.000404

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GARRETT AND DUNNER
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EXAMINER	
PARKIN, J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/19/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 08/067,148	Applicant(s) Montagnier et al.
	Examiner Jeffrey S. Parkin, Ph.D.	Group Art Unit 1648

☒ Responsive to communication(s) filed on *3 Jun 1998* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *29-31 and 37-44* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *29-31 and 37-44* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of the amendment filed 03 June, 1998, wherein claims 15, 16, and 18-20 were canceled without prejudice or disclaimer, claims 29 and 30 amended, and new claims 37-44 submitted. Claims 29-31 and 37-44 are pending in the instant application.

35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29-31 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 29-31 are drawn toward purified immunological complexes comprising an HIV-1 protein (e.g., p12 or p18) and antibody that binds to said protein. Applicants traverse and submit that an improper legal standard is being applied. Reference was made to *Ralston Purina Co.* v. *Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) and *In re Wright*, 866 F.2d 422, 424, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989). It was also argued that one must consider the full scope of the disclosure, working examples, and

stated objectives to ascertain if the written description requirement has been met. Applicants further assert, *inter alia*, that the disclosure teaches the purification of immunocomplexes formed by the interaction of patient sera and viral antigens present in extracts (page 12, paragraph 2), various immunological assay formats (page 14, paragraph 2), and detailed procedures for purifying immunocomplexes between HIV-1 extracts and HIV-1 antibodies (page 14, lines 17-26). These arguments have been carefully considered but are deemed to be nonpersuasive for the reasons of record in paper no. 36 and as further elaborated below.

As previously set forth, this rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in possession of the claimed immunological complexes at the time of the filing date relied upon. Contrary to applicants assertions, the disclosure fails to provide any demonstrative evidence that applicants had generated the claimed immune complexes. Moreover, applicants' references to different portions of the specification is confusing, since those regions failed to clearly state that applicants contemplated making and using purified immunological complexes comprising a viral antigen and antibody. Pages 12 and 14 fail to disclose the preparation and use of the claimed immunological complexes. Page 12 refers to viral extracts containing p25, p18, and p12. Page 14 refers to different immunoassays that can employ the aforementioned antigens. However, neither page of the disclosure describes the isolation and purification of viral antigen/antibody immune complexes and their use for any given purpose. As previously noted, the disclosure only refers to subject matter directed toward a newly isolated virus, the antigens p13, p18, and p25 (refer to disclosure, page 6). The disclosure describes the isolation, purification, and propagation of this virus, subsequently designated LAV. However, there is no indication that applicants actually contemplated making and/or using

the claimed immune complexes. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Applicants may obviate the rejection by providing objective scientific evidence demonstrating that they were in possession of the claimed purified immunological complexes. Absent such evidence, the rejection is hereby maintained.

Non-statutory Double Patenting

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969); *In re Vogel,* 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); *In re Van Ornum,* 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Longi,* 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); and *In re Goodman,* 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

5. The previous rejection of claims 18-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 10-13, and 18-22 (refer to Appendix A) of U.S. Patent No. 5,135,864, is moot in view of applicants' amendment.

6. The previous rejection of claims 15, 16, 18, and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, and 9-11 (refer to Appendix A) of U.S. Patent No. 5,217,861, is moot in view of applicants' amendment.

New Grounds of Rejection

7. Newly submitted claims 37-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 37-44 are directed toward antibodies that recognize HIV-1 p12, p18, mixtures of antibodies that bind p12 and p25, mixtures of antibodies that bind p18 and p25, and mixtures of antibodies that recognize p12, p15, p18, p25, p36, p42, and p80. Applicants traverse and submit that an improper legal standard is being applied. Reference was made to *Ralston Purina Co.* v. *Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) and *In re Wright*, 866 F.2d 422, 424, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989). It was also argued that one must consider the full scope of the disclosure, working examples, and stated objectives to ascertain if the written description requirement has been met. Applicants further assert, *inter alia*, that the disclosure teaches the production of antibodies in animals or the preparation of monoclonal antibodies directed against the claimed viral antigens (pages 30-31, bridging paragraph), as well as detailed procedures for preparing these antigens (pages 11-13 and 21-23). These arguments have been carefully considered but are deemed to be nonpersuasive for the reasons of record in paper no. 36 and as further elaborated below.

As previously set forth, this rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in possession of the claimed antibodies at the time of the filing date relied upon. Contrary to applicants assertions, the disclosure fails to provide any demonstrative evidence that applicants had generated the claimed antibodies. The reference made by applicants to different portions of the specification is confusing, since those regions failed to clearly state that applicants contemplated making and using the specific antibodies. These portions of the disclosure describe the preparation of the viral antigens p12, p25, and p18. The preparation of polyclonal or monoclonal antisera specific for these antigens is not described. As previously discussed, the disclosure only refers to subject matter directed toward a newly isolated virus, the antigens p13, p18, and p25 (refer to disclosure, page 6). The disclosure describes the isolation, purification, and propagation of this virus, subsequently designated LAV. However, there is no indication that applicants actually contemplated making and/or using the claimed polyclonal and monoclonal antibodies. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Applicants may obviate the rejection by providing objective scientific evidence demonstrating that they were in possession of the claimed antibodies. Absent such evidence, the rejection is maintained.

35 U.S.C. § 112, Second Paragraph

8. Claims 37-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that

applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims reference antigens having various molecular weights which is confusing, since it is not readily manifest if applicants are referring to viral antigens or cellular antigens that may be present in cellular or viral extracts. Applicants may obviate the rejection by amending the claim language to indicate that the antigens are LAV, or HIV-1, antigens and that the antibodies are specific to these antigens. The claims also refer to antibodies made by extracts containing these antigens which is confusing. Antibodies are generated in response to the immunization of a suitable host with any given immunogenic composition comprising the antigen(s) of interest. Applicants may obviate the rejection by amending the claim language to indicate that the antibody is specific to the antigen of interest (i.e., An antibody specific for the HIV-1 antigen p12) and is generated in response to the immunization of a host with the proper immunogen (i.e., . . . wherein said antibody is generated by immunizing a host with an immunogenic composition comprising the antigen of interest).

Non-statutory Double Patenting

9. Newly submitted claims 37-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 10-13, and 18-22 (refer to Appendix A) of U.S. Patent No. 5,135,864. The claims of the '864 patent disclose the HIV-1 antigens p15, p25, p36, p42, and p80. Applicants submit that the claims of the instant application are patentably distinct from the claims of the '864 application. Applicants' arguments have been thoroughly considered but are deemed to be nonpersuasive. It is the present examiner's contention that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the

invention was made to generate antibodies against these proteins to facilitate the detection of HIV-1. One of ordinary skill in the art would be motivated to use these antibodies either alone, or in combination, for diagnostic purposes.

10. Newly submitted claims 37-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, and 9-11 (refer to Appendix A) of U.S. Patent No. 5,217,861. The claims of the '861 patent disclose the HIV-1 antigens p12, p18, and p25. Applicants submit that the claims of the instant application are patentably distinct from the claims of the '864 application. Applicants' arguments have been thoroughly considered but are deemed to be nonpersuasive. It is the present examiner's contention that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to generate antibodies against these proteins to facilitate the detection of HIV-1. One of ordinary skill in the art would be motivated to use these antibodies either alone, or in combination, for diagnostic purposes.

Finality of Office Action

11. Applicant's amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R.

§ 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

12. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

13. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached at (703) 308-0570. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

13 August, 1998

Appendix A

92:63788 Human Immunodeficiency Virus (HIV) associated with Acquired Immuno Deficiency Syndrome (AIDS), a diagnostic method for aids and pre-aids, and a kit therefor.
Montagnier, Luc, Le Plessis Robinson, France
Chermann, Jean-Claude, Elancourt, France
Barre-Sinoussi, Francoise, Issy Les Moulineaux, France
Brun-Vezinet, Francoise, Paris, France
Rouzioux, Christine, Paris, France
Rozenbaum, Willy, Paris, France
Dauguet, Charles, Paris, France
Gruest, Jacqueline, L'Hay Les Roses, France
Nugeyre, Marie-Therese, Paris, France
Rey, Francoise, Paris, France
Axler-Blin, Claudine, Paris, France
Chamaret, Solange, Paris, France
Gallo, Robert C., Bethesda, MD, United States
Popovic, Mikulas, Bethesda, MD, United States
Sarngadharan, Mangalasseril G., Vienna, VA, United States
Institut Pasteur, Paris Cedex, France (non-U.S. corporation)The United States of America as represented by the Secretary of The Department of Health and Human Services, Washington, DC, United States (U.S. government)
US 5135864 920804
APPLICATION: US 87-117937 871105 (7)
DOCUMENT TYPE: Utility.
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
CLM What is claimed is:

6. An antigen of said mixture as claimed in claim 5, wherein said protein is p25 protein of HIV.

10. A structural protein of said mixture as claimed in claim 7, wherein said protein is p15 protein of HIV.

11. A structural protein of said mixture as claimed in claim 7, wherein said protein is p36 protein of HIV.

12. A structural protein of said mixture as claimed in claim 7, wherein said protein is p42 protein of HIV.

13. A structural protein of said mixture as claimed in claim 7, wherein said protein is p80 protein of HIV.

18. Retroviral extract as claimed in claim 17, wherein said extract comprises p25 protein of said retrovirus.

19. Retroviral extract as claimed in claim 17, wherein said extract comprises p15 protein of said retrovirus.

20. Retroviral extract as claimed in claim 17, wherein said extract comprises p25 protein of said retrovirus.

21. Retroviral extract as claimed in claim 17, wherein said extract comprises p36 protein of said retrovirus.

22. Retroviral extract as claimed in claim 17, wherein said extract comprises p80 protein of said retrovirus.

L1 ANSWER 24 OF 42 USPATFULL
93:46308 Antigen of a human retrovirus, namely p18 protein of human immunodeficiency virus (HIV), compositions containing the antigen, a diagnostic method for detecting acquired immune deficiency syndrome (AIDS) and pre-AIDS and a kit therefor.
Montagnier, Luc, Le Plessis-Robinson, France
Chermann, Jean-Claude, Elancourt, France
Barre-Sinoussi, Francoise, Issy les Moulineaux, France
Vezinet-Brun, Francoise, Paris, France
Rouzioux, Christine, Paris, France
Rozenbaum, Willy, Paris, France
Dauguet, Charles, Paris, France
Gruest, Jacqueline, L'Hay les Roses, France
Nugeyre, Marie-Theresa, Paris, France
Rey, Francoise, Paris, France
Axler-Blin, Claudine, Paris, France
Chamaret, Solange, Paris, France
Institut Pasteur, France (non-U.S. corporation)
US 5217861 930608
APPLICATION: US 88-158073 880212 (7)
PRIORITY: GB 83-24800 830915
ZA 84-7005 840916
DOCUMENT TYPE: Utility.
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
CLM What is claimed is:

4. Structural protein of Human Immunodeficiency Virus (HIV), which is p18 protein of said virus, and said protein is in isolated form.

5. A labeled polypeptide, wherein the polypeptide is capable of being immunologically recognized by serum of a patient afflicted with Lymphadenopathy Syndrome (LAS) or Acquired Immune Deficiency Syndrome (AIDS); the polypeptide is p18 protein of Human Immunodeficiency Virus (HIV) in isolated form; and said label is an immunoassay label selected from the group consisting of a radioactive label, an enzyme label, and a fluorescent label.

7. An isolated mixture of structural proteins of Human Immunodeficiency Virus (HIV), wherein the proteins are p18 and p25 proteins.

9. Structural protein of Human Immunodeficiency Virus (HIV), which is p12 protein of said virus, and said protein is in isolated form.

10. A labeled polypeptide, wherein the polypeptide is capable of being immunologically recognized by antibodies in the serum of a patient afflicted with Lymphadenopathy Syndrome (LAS) or Acquired Immune Deficiency Syndrome (AIDS); the polypeptide is p12 protein of Human Immunodeficiency Virus (HIV) in isolated form; and said label is an immunoassay label selected from the group consisting of a radioactive label, an enzyme label, and a fluorescent label.

11. A mixture of structural proteins of Human Immunodeficiency Virus (HIV), wherein the proteins are selected from the group consisting of p12, p18, and p25 proteins, and the mixture is in isolated form.